EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: ***Terri Freeman, et al v. Ethicon, Inc., et al.*** **Case No. 2:13-cv-24578**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

EXPERT REPORT OF DR. RICHARD BERCIK

I have been asked to review the medical records, filing documents, and Ethicon corporate documents in the case of Terri Freeman v. Ethicon, Inc. and to render an opinion on the nature and cause of her pelvic injuries. In addition to the medical review, I have also brought to bear my education, training and experience, including familiarity with the medical literature, in reaching my conclusions. My medical opinions rendered in this report are all held to a reasonable degree of medical certainty, based on scientifically reliable evidence.

I. Background and Education

I am a full-time Assistant Professor at the Yale School of Medicine in the Department of Obstetrics, Gynecology and Reproductive Sciences and in the Department of Urology. I am a Fellow of the American College of Obstetrics and Gynecology, and Board-Certified by the American Board of Obstetrics and Gynecology in General Obstetrics and Gynecology and Female Pelvic Medicine and Reconstructive Surgery. I practice Urogynecology and Reconstructive Pelvic Surgery in the Ob/Gyn department at Yale School of Medicine and am licensed to practice medicine in the states of New York, New Jersey, Florida and Connecticut. I received my certification in Female Pelvic Medicine and Reconstructive Surgery in June of 2013. I am currently the Director of Urogynecology at Bridgeport Hospital and faculty at Yale School of Medicine.

I completed my undergraduate studies in Biology from Georgetown University in 1979 graduating cum laude and Phi Beta Kappa. In 1983, I obtained my medical degree from the UMDNJ - New Jersey Medical School, and then completed an Obstetrics and Gynecology residency at New York

University-Bellevue medical Center in New York City. I remained at NYU-Bellevue as a faculty member instructing residents and fellows in advanced gynecologic surgery, incontinence evaluation and management, and pelvic reconstructive procedures, and was the Director of Gynecology and Chief of Service of OB/GYN at Bellevue Hospital Center in New York City, and Co-Director of the Urogynecology/Pelvic Reconstructive Surgery Service at Bellevue prior to joining the Yale faculty. In those positions I have regularly evaluated and managed patients with Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP). I have extensive experience with vaginal, laparoscopic, and abdominal reconstructive procedures for conditions including urinary incontinence, fecal incontinence, pelvic organ prolapse, and vaginal fistulae. I have trained over 250 resident physicians, 25 FPMRS fellows, and over 75 Board Certified OB/GYN physicians in these techniques.

I was appointed to the NICHD Review Committee for RFA HD-00-012, Epidemiologic Research on Pelvic Floor Disorders in 2001. This committee reviewed and recommended applications for research grants by the NICHD branch of the NIH. In addition, I am an active member of several professional associations; American College of Obstetrics and Gynecology, Fellow, American Urogynecology Society, Connecticut Medical Society, New Haven Obstetric Society, Yale Obstetrics and Gynecology Society and Bellevue Obstetrics and Gynecology Society.

I have participated in NIH-sponsored research protocols and have published articles relating to the management of urinary incontinence, pelvic organ prolapse, mesh use and complications, and vaginal fistulae. I served as secondary investigator for TYCO Healthcare on the IVS Tunneller Device for Stress Incontinence and Apical Vaginal Prolapse: A Multi-center Trial. I was a site principal investigator for two FDA –audited 522 studies regarding vaginal mesh sponsored by Astora Medical (formerly AMS). I continue to direct clinical research in new modalities for the treatment of pelvic organ prolapse and urinary incontinence at Yale and I have been invited to lecture both nationally and internationally. I am a site principal investigator for Coloplast trial entitled “Restorelle Transvaginal Mesh Versus Native Tissue Repair, Restorelle 522 study”.

In my clinical practice, I have performed more than four thousand surgeries for treatment of pelvic organ prolapse and stress urinary incontinence. Over two thousand of these procedures utilized mesh insertion techniques. I have implanted over 1500 mid-urethral mesh slings including retropubic, transobturator, and single incision slings and I have trained residents, fellows, and attending physicians to perform mid-urethral mesh slings procedures. I have performed over 600 vaginal mesh procedures, including over 350 Prolift meshes, and I have trained residents, fellows, and attending physicians to perform Prolift vaginal mesh procedures. I have acted as a proctor teaching other attending physicians how to implant and use both slings and vaginal mesh kits for pelvic organ prolapse. I have been a proctor for Gynecare (Prolift), Bard (and Avaulta Solo), and AMS/Astora (Apogee, Perigee, SPARC, MONARC, Elevate, Straight-In, Mini-Arc). In this capacity I have trained physicians to implant Prolift devices on multiple occasions. I am familiar with the TVT-O system through my training for and use of similar devices, material presented by

Ethicon representatives, trial use of the device in the cadaver lab, trial implantation of the device in the operating room, the IFU for the device, and the medical literature.

I have explanted more than three hundred and fifty synthetic meshes over the course of my practice. I have explanted the Prolift +M Anterior and Prolift +M Posterior devices and TVT-O device on multiple occasions. I have explanted over 50 Prolift devices. Some of these were my patients in whom I had inserted the devices and others were referred to me for care. I confirmed the device type based upon review of the insertion surgical report, patient medical records, and my findings at surgery. I routinely teach students, residents, Fellows in Female Pelvic Medicine and Reconstructive Surgery, and colleague surgeons the techniques that may be attempted for the explanting of vaginal mesh and sub-urethral slings (retropubic, obturator, and single incision subtypes).

The methodology through which I reached my conclusions is consistent with my clinical and academic practice. I regularly treat patients with mesh-related complications and regularly determine the etiology of those symptoms utilizing differential diagnoses and other widely accepted medical techniques. In arriving at my conclusions set forth herein regarding the cause of Mrs. Freeman's injuries, I utilized my education, experience, and training in conducting a differential diagnosis/etiology of the injuries and symptoms at issue. In so doing, I "ruled in" potential causes of each injury and then proceeded to exclude other possible causes until, through the process of elimination, I arrived at the most likely cause. As to my opinions regarding the care provided to Mrs. Freeman, I relied on my education, training, and experience, which give me extensive knowledge of the techniques and procedures involved in treating pelvic floor/urogynecological issues. I also relied on my familiarity and review of the techniques and procedures set forth in the Ethicon IFUs for the Prolift+M and TVT-O devices, as well as from my involvement in professional education, and familiarity with internal documents of Ethicon employees and consultants. For my opinions regarding Mrs. Freeman's future prognosis, I utilized the same diagnostic techniques and familiarity with the physiology of the body that I utilize in my regular medical practice. All of the techniques that I utilized are broadly accepted in the medical profession. My Curriculum Vitae is attached as Exhibit A to my report. Exhibit B contains a list of documents that I relied upon in reaching my conclusions.

II. Clinical Summary

Terri Freeman underwent implantation of an Anterior Prolift+M device, Posterior Prolift+M device, and TVT-O suburethral sling and cystoscopy by Thomas Easter, M.D. on 04/08/200 for the diagnoses of cystocele, rectocele, and vaginal prolapse and stress urinary incontinence. At the time she was 57 years old, and was taking medication for hypertension (Zestril), and GERD (Prilosec. Her surgical history included total abdominal hysterectomy and BSO (1979), cardiac ablation (2006). cholecystectomy, and appendectomy. She was a non-smoker.

Below are the significant medical encounters relating to this procedure.

01/28/10 Office visit with Dr. Easter for vaginal prolapse of 3 months duration and has bulge and discomfort. Bulge is lemon size. Patient denies any recent pelvic pain. Exam revealed the bladder was non tender. Assessment: Cystocele and rectocele. Plan Prolift A+P, possible TVT-Secur.

04/07/10 Office visit with Dr. Easter for follow-up. Exam was consistent with cystocele and rectovaginal septum bulging was present. Assessment: Cystocele and rectocele. Plan Prolift A+P, possible TVT- Secur.

04/09/10 Surgery by Dr. Easter included "Anterior posterior colporrhaphy with mesh. Sacrospinous vault suspension with placement of tension free vaginal tape obturator sling." Diagnoses were cystocele, rectocele, vaginal prolapse, and urinary incontinence. The procedure was performed within the standard of care with no evidence of surgeon error or deviation from the procedural steps. The operative note documents the use of hydro-dissection, describes an appropriate vaginal dissection, proper placement and fixation of the mesh in the anterior and posterior compartments, proper tensioning of the mesh, and no trimming of the vaginal mucosa. The TVT-O procedure was performed within the standard of care with no evidence of surgeon error or deviation from the procedural steps. The operative note documents the use of wing catheter guide, proper placement and tensioning of the sling, normal cystoscopic exam, no trimming of the vaginal mucosa, and the use of estrogen vaginal cream packing at the end of the procedure. There was no evidence of any significant surgical complications, episodes of hypoxemia, excess blood loss, excess surgical duration, or surgical site contamination in the records.

04/12/10 Postop office visit with Dr. Easter for incisional pain. No intervention.

04/16/10 Office visit with Dr. Easter for post-op care. Pelvic pain is slightly better, and no fever or chills are present. Abdominal exam and pelvic exam are normal. Assessment is a normal post-op visit.

04/23/10 Office visit with Dr. Easter for post-op care. Normal post-op visit.

04/30/10 Office visit with Dr. Easter for post-op care. Postoperative suture line was slightly inflamed and tender to palpation. No mesh exposure was noted. Assessment included post-operative infection and Levaquin and Diflucan was started.

05/17/10 Office visit with Dr. Easter for vaginal discharge and spotting. The exam is unchanged, and HRT was started.

06/2/10 Office visit with Dr. Easter. No complaints. Abdominal and vaginal exams are unremarkable. No discharge is noted.

07/07/10 Office visit with Dr. Easter for light vaginal discharge. No mesh exposure is noted, granulation tissue was present and treated with AGNO3.

08/16/10 Office visit with Dr. Easter. HRT pellet placed.

10/25/10 Emergency Department visit at San Antonio Hospital for RUQ and RLQ pain. Had burning with urination and in the vaginal area. History of right flank pain radiating to the vagina. Noted is difficulty with emptying the bladder during the past month. Denied vaginal bleeding or discharge. Tender on pelvic exam assessed as inflammation from surgery, but not PID since pain was mild. CT scan does not show cause of pain. Treated with Dilaudid and Toradol.

10/26/10 Office visit with Dr. Easter for Pelvic pain for 2 days with sudden onset, right sided, RLQ, Pain is 8/10, throbbing and sharp. On exam bladder nontender and the perineum was normal.

05/27/11 Visit with Dr. Sung Kim. Complained of bladder discomfort and mild hematuria. Was on Bactrim x 10 days. Urine culture was consistent with a UTI and Mrs. Freeman was treated with Macrobid (organism was resistant to Bactrim).

02/06/13 Office visit with Dr. Easter for 2 years of vaginal discharge with a foul smell and vulvar burning. Had itching, irritation, and dyspareunia. Exam was consistent with atrophic vaginitis. Referred for pelvic PT.

07/03/13 Office visit with Dr. Easter for severe vaginal pain and vulvar swelling. Assessment is pelvic pain. Plan is for diagnostic laparoscopy and “resection of constricted vaginal mesh”. CT scan was unremarkable for pelvic or abdominal pathology.

07/05/13 Office visit with Dr. Easter for pelvic pain and dyspareunia. Since her 2010 surgery has had intermittent pain. Pain was severe 2 weeks before visit. Exam reveals a normal abdominal exam, vaginal cuff pain, marked pain in the left vaginal sidewall with palpation. Suprapubic tenderness to palpation also was present. Assessment was pelvic pain and the plan was diagnostic laparoscopy and resection of vaginal scar.

07/09/13 San Antonio Hospital - Diagnostic laparoscopy with transvaginal resection of mesh and scar tissue is performed. H&P documents marked tenderness to palpation to the left pelvic sidewall. Indications are Pelvic pain and Dyspareunia. Diagnostic laparoscopy with transvaginal resection of mesh and scar tissue. There was no evidence of endometriosis. No adhesions noted. No abnormalities in the upper abdomen; noted were adhesions of the transverse colon to the anterior abdominal wall. With palpation of the left vaginal wall, where pain had been elicited, a linear incision was made in the vaginal wall. Using blunt dissection, a band of mesh from a prior mesh placement was identified. This was cleaned of fibrous tissue, and a segment approximately 2 cm in length was excised. Cystoscopy was normal.

07/23/13 Office visit with Dr. Easter for post op care; normal exam with bladder and vaginal not tender.

07/29/13 Office visit with Dr. Easter for pain and discharge from abdominal incision. Erythema and tenderness noted at the incision. Treatment was moist heat to the incision.

07/30/15 Office visit with Dr. Easter for pelvic pain of 2 months duration which was progressively getting worse. Pain is located in the vaginal region, 7/10 severity, with a pressure and pulling quality. No fever or chills noted. Vaginal exam showed no masses or inflammation. Plan was to schedule a steroid injection to the left vaginal wall.

08/02/15 San Antonio Ambulatory Surgery Center. Colonoscopy and EGD for abdominal pain revealed diverticulosis and gastritis. No colonic polyps, masses, strictures or A-V malformations were noted.

11/17/15 Office visit with Dr. Easter for pelvic pain. Noted is an increase in pain with postural changes and sexual intercourse. Exam revealed intractable pain and pelvic floor spasm with palpation of upper vaginal sulci. Assessment was dyspareunia and pelvic pain. Steroid injection with Marcaine and Kenalog into vaginal walls done. Plan was to schedule transvaginal removal of pelvic floor mesh and possible exploratory laparotomy.

12/02/2015 Office visit with Dr. Easter to discuss surgery for pelvic pain and dyspareunia. Plan for transvaginal removal of pelvic floor mesh.

12/28/2015 San Antonio Hospital- Dr. Easter performs Transvaginal resection of anterior and posterior pelvic floor mesh and cystoscopy. Diagnoses are Pelvic pain with dyspareunia. Described is that for posterior removal: "Undermining the mesh with Metzenbaum scissors from the introitus up to near the apex of the vaginal canal on the posterior floor. The mesh was transected after placing a right-angle retractor underneath the mesh and elevating the mesh with careful attention to avoid the rectum. The lateral arms of the mesh were dissected out by sharp and blunt dissection after which the arms of the mesh were cut near the uterosacral ligaments. This was carried out bilaterally with removal of the posterior floor mesh both right and left sides. Anterior removal described …" with a midline incision the bladder was dissected away from the overlying vaginal epithelium. The paravesical space was entered. There was no evidence of any mesh on the bladder wall on the right. However, there was mesh extending towards the midline on the left. This was dissected away and then tracing the mesh out towards the obturator membrane the arms of the mesh were transected and removed on the left. No mesh could be identified on the right therefore with palpation the arms of the previously placed mesh were palpated, and these were cut releasing tension on the apex of the vagina." Pathology report returned: right posterior mesh 7.5x 2.0x 0.5 cm, left posterior mesh 7 x 2x 0.3 cm., Left anterior mesh 7 x 2 x 0.4 cm.

12/31/15 Office visit with Dr. Easter for post-op care and catheter removal. Denies fever or problems with the catheter.

1/12/16 Office visit with Dr. Easter for post-op care. Patient reported vaginal pain, fever and discharge. Vaginal exam did not show discharge or signs of infection, mesh exposure, or bleeding.

01/24/16 Readmit to San Antonio Hospital for pelvic pain with possible pelvic abscess. Complained of constipation and, vaginal and rectal discharge, dizziness, and cloudy, foul-smelling urine. Exam showed abdominal and suprapubic tenderness. Zosyn IV started. CT Scan abdomen/pelvis showed 5.0 x 2.7 cm rim-enhancing pelvic fluid collection to the left of the rectum which abuts the cervix. More superiorly, and to the left of the rectum, there are 2 small ovoid fluid collections which measure 2.9 x 1.3 cm in conglomeration. These do not abut the adjacent rectum.

01/25/16 San Antonio Hospital. ID Consult for possible pelvic abscess documents. “63-year-old female with history of hypertension, arrhythmia, and pelvic pain with dyspareunia, who underwent a transvaginal resection of mesh on 12/28/2015. Patient states that since the surgery, she has not been feeling well and not herself. She states that she has been complaining of constipation since a bladder sling was implanted with occasional diaphoresis, dizziness, and cloudy urine. She also reports that she has been having discharge in her rectal and vaginal area, same color. It is dark brown, foul-odorous, but not stool. She states that, within the last 2 days, she had such difficulty having a bowel movement and was in so much pain that she decided to come to the ER for further evaluation.” Upon admission to the ED, she was found to have a temperature of 97.8, blood pressure 145/93, pulse 81, respirations 20, saturations of 98% on room air. They did laboratories which did not show any significant leukocytosis, but they did a CT of the abdomen and pelvis that showed that she has a 5 x 2.7 fluid collection in the pelvis. Patient has been admitted and is now scheduled for ultrasound-guided drainage of this fluid collection. Currently, the patient states she still does not feel well and not herself, still has some rectal pain. IV Zosyn was continued.

01/25/16 San Antonio Hospital. Endovaginal approach pelvic abscess drainage was performed. Approximately 20mL of dark bloody colored liquefied fluid was removed and the culture grew Prevotella loeschii (Bacteroides melaninogenicus).

1/31/16 San Antonio Hospital Emergency visit for constipation. Pelvic CT scan done. on the left side adjacent to the vaginal cuff there is an abnormal fluid collection which measures 3.1 x 2.1 cm. On 1/24/16 this measured 6.1 x 3.0 cm. This was drained on 1/25/16. There are 2 additional small fluid collections seen more superiorly in the pelvis on the left side. These measure 1.9 x 1.5 cm and 1.4 x 0.9 cm. These are not significantly changed. Discharged with follow up.

02/01/16 Office visit Dr. Abdelkarim for constipation. Documented is fecal impaction requiring manual disimpaction. Due to concern for fistula a barium enema was ordered.

02/04/16 San Antonio Hospital. Barium Enema done to check for fistula, Results are…No fistula, extravasation, or vaginal contrast was observed to suggest a rectovaginal fistula

02/11/16 Office visit with Dr. Easter for post-op care. No complaint, fever, or chills. Vaginal exam shows incisions are healing well.

03/09/16 Office visit with Dr. Easter for post-op care. Reported is urinary frequency and dysuria for 4 weeks. Exam revealed normal vaginal diameter, and no obvious discomfort. Vaginal dilator therapy was ordered.

04/12/16 Office visit with Dr. Easter for post-op care. Reported is that the patient needs to strain in order to urinate and that this has been a problem since surgery. Exam was normal and Myrbetriq 50mg was ordered.

05/19/16 Visit with Dr. Tasia (San Antonio Urology Group) for urinary retention after mesh complications. Patient reports need to push to void. Also noted is still has dyspareunia, no vaginal discharge and no hematuria or UTIs. Vaginal exam notes general tenderness to anterior palpation, no mesh erosion, sling is palpable but no other mesh palpated. A pocket just inside the introitus extending in the perineum is noted. but it does not appear to communicate to the rectum. PVR by bladder scan was 254cc. Assessment was urinary retention and cystocele. Plan was for cystoscopy, ultrasound, and possibly urodynamics.

05/23/16 Office visit with Dr. Easter for removal of catheter. Catheter was placed for urinary retention.

05/23/16 San Antonio Urology -Renal ultrasound done. Small simple cyst in the left kidney. The kidneys are otherwise normal. Increased post void residual within the urinary bladder. Post void bladder volume 165 mL. Cystoscopy was performed with normal findings.

06/02/16 Office visit with Dr. Easter for post-op care. Bladder pain is reported. No pelvic exam is documented. Patient was referred to Dr. Sam Siddighi for bladder dysfunction.

07/11/16 Loma Linda University. Pre-operative evaluation documents the following:

63-year-old patient who has an extensive history of surgery. She had a transvaginal mesh sling as well as a prolapse mesh kit used from Johnson and Johnson in 2010. Then, in July of 2013, she had a diagnostic laparoscopy, part of the transvaginal mesh was removed. Then, again in December of 2015, she had the rest of the transvaginal mesh removed. The patient says since the last surgery she has not been able to empty her bladder well. She has seen two urologists. She had urodynamics done on June of 2016. She demonstrated a void of 72 with a postvoid residual of 248 to max 5 mL/minute. Thus, the patient does have objective signs of voiding dysfunction. She denies any urinary incontinence. She says when she voids, she has to bend down, has intermittent voiding and she feels like she has at least half left in her bladder. She denies any real

defecatory dysfunction. She is sexually active but does have dyspareunia and only has had sex 5 times in the last 6 years. She feels that it is due to the pain in the vagina from the mesh surgeries.

PELVIC: External genitalia and urethral meatus are normal. Urethra and bladder are normal. She has a grade 0-1 anterior wall descent, grade 0-1 posterior wall descent. The rest of the vaginal wall is well supported. However, she had a lot of tenderness in the vagina on palpation, especially on the apex there was some scar tissue and on the anterior wall near the apex. She has a two finger caliber introitus. I do not feel any mesh erosion. There is also a small hole in the left distal introitus, which goes down to the rectum, but there is no connection into the rectum.

On multichannel urodynamic, she does have some increased pressure with low flow and has an elevated postvoid residual of 280 mL after voiding 414. On cystoscopy, bladder walls were inspected systematically. All the walls were within normal limits. The bas-fond and trigone were normal. Ureteral orifices were seen bilaterally. Spill was noted on both sides. I did not see any mesh in the bladder. We repeated the postvoid. Today she voided 325 mL, had a postvoid residual of 290 mL. The patient states that she Valsalvas (sic) every time she voids, and again, has dyspareunia and uses a dilator.

07/11/16 Loma Linda University Medical Center (LLUMC) Dr. Siddighi, Operative Report documents the following:

Diagnoses are Urinary retention, Dyspareunia, and Vaginal scar tissue. Procedure done is sling revision, excision of vaginal scar tissue, posterior repair, and cystoscopy.

Findings include: “Before surgery, small introitus. There is a hole in the distal left posterior wall to the rectum but not a fistula, and copious scar tissue in the posterior anterior wall. During surgery, tight blue sling midurethral area. Intrapelvic portion was removed. There is no foreign body in bladder or urethra. Bilateral spill of urine on cystoscopy. After surgery, good length and excellent caliber. No constriction rings and normal rectal examination.” Also described was a “posterior vaginal wall introital band” requiring the dissection of scar tissue in this area. Pathology report documents specimen labeled “mesh suburethral” as 4 fragments ranging in 0.6 to 2.5 cm in greatest diameter with blue thread woven throughout. Specimen labeled perirectal scar tissue is 2.2x 1.5 x.0.8 cm tan soft tissue.

07/16/16 LLUMC ER VISIT for post-operative vaginal bleeding after "felt something pop". Documented is “Patient had sling release and posterior repair surgery on 7/11/2016. Patient did well postoperative with mild postoperative bleeding. Patient was sent home with Foley catheter due to inability to empty bladder completely. Patient presents today with complaint of persistent vaginal bleeding with intermittent bright red bleeding and dark blood with small clots. On exam is noted “suture from posterior repair and sling reversal anterior repair noted. There was no active bleeding however there was small ~ 1cm area of posterior repair that appears to have a loosed suture with raw tissue exposed with oozing dark blood with small clot.”Silver nitrate-controlled bleeding and patient was discharged.

10/13/16 LLUMC Visit for Physical Therapy. Documented is Chief Complaint: pain in the buttock region, leak urine when I try to get out of bed and have strong urges and bending will make it squirt out, difficulty emptying my bladder

Mrs. Freeman described the following:

"The scar tissue had drawn everything in and I'm very small in vaginal opening, everything has pulled in. The bladder sling got too tight, wasn't emptying my bladder, Dr. Siddighi removed the bladder sling 7/2016, he said again I was heavily scarred, and I think I'm having nerve pain, Dr. Siddighi thinks its muscle pain. Get really sharp pain in the buttock and it just stinking hurts and started after the surgery in 7/2016, the pain is in the sacral area."

Also noted is "Current **level of function:** When I have the pain can't vacuum, dusting, mopping. Can't play with grand-kids. Can just sit and try to wait it out. Just sit on the couch and rest."

Assessment: Patient presents with reported symptoms consistent with soft tissue mobility deficit, scar tissue, with most probable high nerve irritability and a centralized pain component. Will continue to assess with additional follow-up treatment sessions. Diagnosis is Chronic pelvic pain in female.

10/20/16 LLUMC Visit for Physical Therapy. Exam notes "Maximum TTP L sacrotuberous ligament; L piriformis; L/S paraspinals, Moderate tightness L sacrotuberous ligament Maximum guarding L/S paraspinals." Diagnosis is "Chronic pelvic pain in female.

10/21/16 Office visit with Dr. Ja-Hong Kim (UCLA Medical Center) for mesh complication. The record documents "Terri Freeman is a 64 year-old female with a history of transvaginal mesh placed 4/2010 for cystocele repair and TOT and Prolift complicated by pelvic pain at 3 months post op. She had dyspareunia immediately afterwards. Then she developed pain regardless of activity and had sudden worsening while walking up the stairs in 2013. … For this she underwent transvaginal excision as well as diagnostic laparoscopy. About 2 cm of mesh was removed from vagina and scar lysis was performed. This did not help her at all. She then underwent another mesh excision in 2015 where dissection was carried out to the uterosacral ligaments and obturator space. Then July 2016, TOT sling was removed". The record documents dyspareunia and inability to have intercourse along with pain in the left buttock and gluteal region, and pain with palpation of the vaginal apex. The Pelvic Exam documents Vaginal atrophy severe. Vault tender to palpation; tight vaginal wall, tender throughout, extensive scarring. No anterior vaginal wall mass. No evidence of foreign body/ mesh exposure. Assessment was 64 year-old female with a history of multiple transvaginal procedures for mesh complication - possible chronic inflammation due to infected mesh arms in the obturator space. Plan was to perform cystoscopy, spine MRI, and abdominal/pelvic CT scan.

10/28/16 LLUMC Visit for Physical Therapy. Assessment includes "High nerve irritability and muscle guarding. L OI palpation with maximum tightness and reproduced familiar glut/back pain." Diagnosis is Chronic pelvic pain in female.

11/11/16 LLUMC Visit for Physical Therapy - Pain level on arrival: 4/10 - buttock/sacrum/vaginal shoots of pain, always the left side. Exam - Maximum TTP L sacrotuberous ligament; L piriformis; L/S paraspinals Moderate tightness L sacrotuberous ligament. Maximum guarding L/S paraspinals. Pain was 5/10 buttock and LB. Diagnosis is Chronic pelvic pain in female.

12/21/16 Surgery by Dr. Ja-Hong Kim at UCLA. Preoperative diagnoses listed are history of mesh complication, chronic gluteal pain, dyspareunia, mesh extrusion, and prior mesh excision. Procedures performed were Transvaginal urethrolysis, removal of mesh sling, vaginal reconstruction, bilateral groin dissection, and excision of anterior and posterior mesh.

Described in the operative report is that on exam, the urethra appeared to be hyper-suspended and she also had some pain with palpation of the sling and there was significant vaginal scarring on both anterior and posterior vaginal. On exam, she had puckering of the anterior vaginal wall. On the left side an incision in the groin crease vertically extending from the level of clitoris down to mid vaginal wall of the vagina was created and a hard nodule was palpated and was transected on that side. The mesh arm was dissected by freeing it from muscle attachments. There were two additional mesh arms in the vicinity, all entangled together and tethered to the bone. The attachments fixed the mesh arms thereby making the dissection very challenging.

On the right side was identified the small mesh segment as it coursed to the obturator space. A right groin incision was created, but the operator could not identify any mesh. Continued exploration of the right groin did not identify any significant mesh segments. The mesh from the vaginal side was excised and sent it to pathology. A periosteal elevator was used to free the mesh from the bone.

There was also another area of mesh at the posterior vaginal wall at midline. This was also excised and sent off to pathology. Vicryl sutures were placed to bring together the dissected vaginal skin.

Pathology for specimen labeled “Vaginal Mesh” showed tissue 6.0 x 4.0 x 0.5 cm in size. Microscopic diagnosis was “Skin and subcutaneous tissue with moderate chronic inflammation and foreign body reaction.”

01/20/17 Office visit with Dr. Ja-Hong Kim for post-op care. Noted is the patient was doing well initially but with same pain. On exam, she has tight levators; still sutures in place. GU exam - No evidence of prolapse; tight pelvic floor; tender on palpation; bilateral groin incisions have healed well. Plan was Vaginal valium, Hiprex BID, Ibuprofen as needed, PFT/ scar lysis, UTI prophylaxis, and follow up in 2 months or earlier as needed.

03/02/17 Casa Colina Physical Therapy visit. Documented is pain ranging 4-10/10 which is constant and limits ADLs such as standing, sitting, and walking. Also noted is sensation of a

hardened area- “like a constriction”. Pain was noted in left sacral area and pelvic floor. Diagnosis was Pelvic Floor Muscle Dysfunction.

03/07/17 Casa Colina Physical Therapy visit. Diagnosis was Pelvic Floor Muscle Dysfunction.

03/10/17 Casa Colina Physical Therapy visit for lumbosacral pain.

03/14/17 Casa Colina Physical Therapy visit. Diagnosis was Pelvic Floor Muscle Dysfunction.

03/22/17 Casa Colina Physical Therapy visit for lumbosacral pain

04/24/17 Office visit with Dr. Ja-Hong Kim. Documented is PT visit being completed, plan for pain physician to inject S1/S2, and use of pain patch. Continues to have same pain, lower back, vagina, pelvis. Pain is mainly on the left side. Also having trouble urinating. Has lack of bladder control. Has positional loss of urine (laying to sitting). Feels her urine stream is slow and has to strain excessively. Has to lean forward in order to empty. Continued pain. It is impacting her quality of life. Patient was tearful talking about it.

05/16/17 Office visit with Dr. Ja-Hong Kim. Video Urodynamics (VUDS) and cystoscopy done. The PVR was 60 with slow flow and normal bladder pressure and no detrusor overactivity during voiding. Detrusor overactivity, urge incontinence, and chronic pelvic pain was diagnosed. Plan was to schedule Exploratory laparotomy, Adhesioloysis/Removal of residual mesh anchors Transvaginal urethrolysis-Possible.

06/28/17 Surgery performed by Dr. Ja-Hong Kim. Preoperative diagnoses listed are History of mesh complication s/p removal, Chronic pelvic pain due to mesh, and History of multiple prior abdominal surgeries. Procedures performed were Exploratory laparotomy, Lysis of adhesions, Removal of foreign body, and cystoscopy. No residual mesh was identified. Lysis of bowel adhesions on the right side was performed. Discharged from the hospital on 7/1/17.

07/20/17 Office visit with Dr. Ja-Hong Kim for post-op care. Noted is reduction of left pelvic /buttock pain. No pelvic exam was documented. PVR was 10 ml. Mrs. Freeman was cleared to resume intercourse.

10/27/17 San Antonio Hospital- Pelvic Ultrasound for abdominal and pelvic pain. Impression was negative pelvic ultrasound.

11/30/17 Office visit with Dr. Ja-Hong Kim for follow-up. Complaint of left sided pelvic pain described as a pulling pain. Denies any buttock pain. She is also complaining of a deep lower abdominal pain that is minimally aggravated with deep palpation. Patient states pain feels internal and not a superficial pain. Patient is not performing any stretching exercises or physical therapy programs. Patient has taken Ibuprofen for pain with minimal relief. No fever/chills. Abdominal

exam is normal. No pelvic exam is documented. Sexual activity is not documented. Assessment is that the patient is doing better and physical therapy/exercise I was recommended.

02/15/18 Casa Colina Physical Therapy visit. Diagnoses are pelvic pain, dyspareunia, vaginal pain, Pelvic Floor Muscle Dysfunction.

02/23/18 Casa Colina Physical Therapy visit for abdominal, pelvic, and lumbosacral pain.

02/27/18 Casa Colina Physical Therapy visit for abdominal, pelvic, and lumbosacral pain.

03/13/18 Casa Colina Physical Therapy visit for abdominal, pelvic, and lumbosacral pain.

07/9/18 Office visit with Dr. Ja-Hong Kim for chronic pelvic pain and LUTS (lower urinary tract symptoms). Patient c/o radiating pain from abdomen, to pelvic area, to lower back and down her left leg. Unable to tolerate pain from full body binder. Patient can only tolerate binder for 1 hour. PT recommended she do isometrics, but it causes back pain. Patient is taking 1 Norco QD.

Since last visit she saw OBGYN Dr. Grisales who also PFPT. Urine culture 1/23/18 grew >100K Streptococcus agalactiae and 30K E. coli pan sensitive. Given Keflex by Dr. Grisales but had to stop due to ER visit during acute diverticulitis flare up; switched her to Flagyl and ciprofloxacin. She also saw Neurosurgery, Dr. Pouratian, (6/11/18) who further assessed that chronic pain 2/2 scar tissue and extensive surgical history, and that patient should focus on pain management versus anatomical/surgical intervention.

Sexual activity is not documented. Pelvic exam is not documented.

Assessment is chronic pain of unclear etiology, possible diastasis recti with suggestion of PT and pain management.

08/18/18 San Antonio Hospital- Abdominal /Pelvic CT Scan for diffuse abdominal pain. No evidence of an acute process. Hepatic steatosis. Left hemicolon diverticulosis with no evidence of diverticulitis.

III. CAUSATION OPINIONS

The effective porosity of the Prolift+M device was too small to allow for proper tissue in-growth into the implant. Multiple published sources have demonstrated poor tissue ingrowth with bridging fibrosis and scar-plate formation in tissue when polypropylene mesh pore size is less than 2mm. With pore size < 2mm collagen can completely cover mesh fibers and obliterate inter-fiber spaces not allowing for proper in-growth of vascular and neural structures. Mesh construction requires optimization so that integration within the host tissue results in a more natural repair where the resulting scar plate is reduced and is more elastic to meet biologic requirements. Furthermore, the literature also establishes that the mesh must maintain effective pore sizes, in actual use under

strain/tension of 1 mm or larger to prevent scar plate formation and bridging fibrosis. This decrease in mesh pore size when subjected to forces consistent with physiologic events has been shown to cause collapse of the pores in the mesh implant. The mesh used in the Prolift+M device (Ultrapro) has been shown to have complete loss of effective porosity at physiologic forces and to have no pores > 1mm. in size at the upper range of physiologic forces (Otto et. al). These measurements are below the thresholds described in the literature to be necessary to allow for healthy, biologic, integrated tissue growth. The mesh design results in excess scarring, chronic tissue inflammation/reaction, and loss of elasticity, nerve entrapment, poor vascularity, and tissue rigidity. This is most prevalent where the arms of the mesh meet the central section. It is my clinical experience that pain most often occurs near the support arms, and that upon removal of the vaginal section of these arms the scar tissue and tissue induration encountered is excessive and not physiologic.

The requirement to allow tissue ingrowth and to have minimal tissue fibrosis is documented in Ethicon's internal documents (Levine internal memo 11/10/00) 10 years prior to the Prolift and TVT-O implants performed on Terri Freeman. These tissue reactions/consequences cause dangerous clinical reactions and complications, for example dyspareunia, chronic pelvic pain, hypertonic muscle dysfunction, scar plating, bridging fibrosis, nerve irritation and entrapment, mesh contraction, vaginal narrowing and shortening, reduced local immune response leading to chronic vaginal/urinary infections, voiding dysfunction, defecatory dysfunction, prolapse recurrence, bladder outlet obstruction, and the need for additional treatments/surgeries, which in some cases cannot be safely and effectively carried out.

The Prolift+M mesh is too stiff to allow for proper tissue ingrowth and collagen formation. Elasticity and stiffness are important characteristics of mesh implants especially regarding tissue in-growth and health. The importance of mesh stiffness is documented in Ethicon's documents (Levine internal memo 11/10/00) 10 years prior to the Prolift and TVT- O implants performed on Terri Freeman. Multiple publications in peer-reviewed journals have demonstrated the negative effect of mesh stiffness on target tissue healing, muscle structure and function, and collagen composition. As published in peer-reviewed literature the Prolift+M mesh had high tensile and flexural stiffness values (Feola et, al). This characteristic has been shown to be detrimental to tissue growth, collagen production, smooth muscle structure and function, and the composition of the extracellular matrix (Liang). Increased inflammatory reaction has been shown with stiffer mesh implants. These tissue reactions/consequences cause dangerous clinical reactions and complications, for example dyspareunia, chronic pelvic pain, hypertonic muscle dysfunction, scar plating, bridging fibrosis, nerve irritation and entrapment, mesh contraction, vaginal narrowing and shortening, reduced local immune response leading to chronic vaginal/urinary infections, voiding dysfunction, defecatory dysfunction, prolapse recurrence, bladder outlet obstruction, and the need for additional treatments/surgeries, which in some cases cannot be safely and effectively carried out.

The Prolift+M mesh contracts and shrinks. Mesh contraction is a well-defined occurrence and there are multiple reports in the peer-reviewed literature regarding this consequence of polypropylene mesh. As early as 2005 Cobb et. al noted a 20-50 % reduction in meshes from their original size. The requirement that mesh not result in tissue contracture is documented in Ethicon's internal document (Levine internal memo 11/10/00) 10 years prior to the Prolift+M and TVT-O implants performed on Terri Freeman. Mesh shrinkage resulting in pain and dyspareunia is also

discussed in an Ethicon email from Gene Kammerer to Mora Melican dated 5/1014. This phenomenon of mesh retraction and subsequent dyspareunia was a concern to Ethicon employees as early as 2005. A memo (1/11/2005) from Dr. Axel Arnaud, one of the developers of the Prolift, to Ophelia Berthier, Marketing Director Worldwide at Ethicon, stated:

I suggest to propose to add the following to the new version of the IFU:

> WARNING: Early clinical experience has shown that the use of mesh through a vaginal approach can occasionally/uncommonly lead to complications such as vaginal erosion and retraction which can result in an anatomical distortion of the vaginal cavity that can interfere with sexual intercourse. Clinical data suggest the risk of such a complication is increased in case of associated hysterectomy. This must be taken in consideration when the procedure is planned in a sexually active woman.

This contraction occurs due to scar formation and the healing process. However, when excess scarring, bridging fibrosis, and scar plate formation occurs the contraction is no longer physiologic. This process results in shrinkage and contraction of the mesh implant and leading to increased inflammatory response, poor tissue vascularity, nerve impingement and entrapment, stiff tissue, poor collagen formation, poor wound integrity, and excess tissue tension. Contraction has been shown to be affected by mesh characteristics such as a pore size of less than 1 mm effective porosity in actual use, as seen in the Prolift+M mesh. Mesh contraction and the resultant disordered wound results in nerve irritation and entrapment, vaginal pain, urethral pain, bladder pain, muscle pain, groin pain, hypertonic pelvic floor disorders, dyspareunia, voiding dysfunction, bladder outlet obstruction, severe vaginal scarring, rigid vaginal tissue, vaginal shortening, recurrent vaginal and urinary infection, defecatory dysfunction, recurrence of incontinence, recurrence of pelvic organ prolapse, and required multiple treatments including multiple surgeries, physical therapy, injections, and medications among others. Despite these treatments, to a high degree of medical certainty, patients will not experience complete resolution of their complications (Crosby et al).

The arms of the Prolift+M mesh roll and cord when pulled through the cannula track. The Prolift+M device entailed the placement of a snare device which was a suture loop threaded through a cannula and then used to capture the arms of the mesh implant. These cannulas were placed by use of a trocar which were passed through the obturator structures for the anterior device to access the paravaginal/paravesical space. Similarly, the trocars and cannulas were passed through the pararectal space and penetrated the muscle of the pelvic floor when passed through the sacrospinous ligament. Withdrawal of the suture loop would capture the end of the mesh arm in the cannula. The loop would then be withdrawn through the cannula and the cannula would be removed. The mesh arms were ~12mm in width, yet the cannulas were ~ 6mm in diameter. This mismatch resulted in rolling or curling of the arms. This process further reduced pore size and caused folding of the mesh upon itself, resulting in functionally heavier, denser material with reduced pore size. This will result in greater scar formation and resultant tissue fibrosis, bridging fibrosis, scar plate formation and the resultant effects of these tissue changes, including pain. An internal Ethicon email dated 10/15/10 from Piet Hinoul (Ethicon Medical Director) to Jonathan

Meek (Ethicon Worldwide Marketing Director) identifies the defect in the Prolift+M which results in 45% narrowing in the mesh with applied force. The document states:

"I was at a meeting today where someone approached me to say that Prof Deprest had been at a meeting challenging that indeed we cut the Prolift +M mesh in the wrong direction..."

In response:
"CRAP!!
Didn't expect such a result.
I took the mesh strips home and did the measurements in my home work shop. Given the delta in length and width, we should discuss as a team to kill the longitudinal design given its unacceptable 45% narrowing. Despite the lateral flex orientated graft performing better, it still narrowed over 10% …"

This is consistent with my experience when I have performed dissection for the removal of the Prolift and Prolift+M devices. Excessive scar formation, intense neovascularization, and anatomic distortion are invariably present. The section of mesh which penetrates the obturator/groin structures and is posterior to the descending pubic ramus invariably has an unpredictable degree of scarring much greater than the section of mesh in contact with the vaginal mucosa. This fibrosis results in dense scar formation and mesh contraction resulting in undue tension of the fascia, muscle, and neural elements of the paravaginal, deep pelvic, and obturator / groin spaces. The posterior arms of the Prolift+M which penetrate the muscles of the pelvic floor and the sacrospinous ligament will place these structures under tension with mesh contraction. The result of this is muscle spasm, muscle tension, and High Tone Pelvic Floor Disorder. Clinically, this results in increased rates of lower back pain, vaginal pain, lower abdominal pain, hip pain, buttock pain and dyspareunia in patients when compared to other forms of prolapse repair.

The arms of the Prolift and Prolift+M devices cannot be removed without significant exterior incisions in the groin (anterior) and/or buttock/gluteal regions (posterior), and extensive deep dissection of the paravaginal (anterior) and pararectal (posterior) spaces. The design of the Prolift and Prolift+M devices did not consider the effect of potential removal of the devices for complications. The Prolift+M which was a device launched after the complications Terri Freeman suffered were known to be possible. Nevertheless, no change in design to avoid the use of paravaginal and pararectal supporting arms, which traverse through deep pelvic spaces, were made to the Prolift+M device. Complete removal of the anterior Prolift and Prolift+M devices requires multiple groin incisions, coupled with at least one vaginal incision, and dissection into the deep paravesical and paravaginal spaces which include extensive neural and vascular elements responsible for bladder and urethral function, genital sensation, vaginal function and sensation, and sexual response including orgasm. Extensive dissection into these spaces will, to a degree of medical certainty affect all of these mechanisms. Complete removal of the posterior Prolift and Prolift+M devices requires multiple gluteal incisions, coupled with at least one vaginal incision, and dissection into the deep pararectal and paravaginal spaces which include extensive neural and vascular elements responsible for rectal and anal function, defecatory function, external genital sensation, and vaginal sensation and function. Extensive dissection into these spaces will, to a degree of medical certainty, affect all of these mechanisms. Such a deep dissection could not only result in significant post-operative complications, including pain, but would also necessarily result in vaginal scarring, disfigurement, and risks to neighboring organs. These factors were not

addressed with the design of the Prolift or Prolift +M devices. Terri Freeman required bilateral groin dissection for the removal of the residual Anterior Prolift arms, and the TVT-O sections behind the pubic ramus. Such a deep dissection requires external incisions in the groin areas which could not only result in significant post-operative complications, including pain, but would also necessarily result in vaginal scarring, disfigurement, and risks to neighboring organs. Ethicon was aware of the complications associated with the support arms at least 14 months prior to Terri Freeman's Prolift+M implant procedures. An internal Ethicon email dated 02/12/09 from Peter Meier (Ethicon Health and Urology) to David Robinson (Medical Director Ethicon) states:

> Absorbable distal arms that will reduce discomfort like leg pain, buttock irritation etc. Temporary stress shielding of the graft reduces folding, deformation, crumbling, that lead to erosion, pain etc.

This email clearly identifies, prior to the implant surgery Terri Freeman had on 04/09/10 the unfortunate reality that the Prolift+M and TVT-O devices cannot be safely and effectively removed in many patients as a result of the nature and configuration of the mesh, the locations of implantation, and the intended incorporation of the mesh in the body. The design of the Prolift and Prolift+M devices, which requires passage of mesh through deep spaces and structures in the pelvis, including muscle, fascia, and neural elements, precludes complete excision without extensive and disfiguring surgery. The design of the TVT-O device requires placement near delicate vascular and neural elements, penetration through multiple muscles including groin muscles and hip rotators and requires inflammatory tissue changes and scar formation for the fixation of the device adjacent to these structures. These factors are included in the unreasonably dangerous characteristics and design defects for these devices. Vaginal contraction, vaginal scarring, vaginal distortion, and dyspareunia associated with a Prolift+M implant is likely permanent as a result of the inability to safely remove the Prolift+M in its entirety. The increased rates of chronic, potentially permanent injuries associated the Prolift+M when compared to other treatments for pelvic organ prolapse further supports my opinion that the Prolift+M is defective and that the defective properties of the mesh caused injury to Mrs. Freeman.

I have reviewed the medical records associated with the care and treatment of Terri Freeman. Mrs. Freeman was a candidate for alternative procedures for treatment of her prolapse and stress incontinence, and it is unlikely that she would have suffered the complications she has suffered if alternatives had been employed – this is especially true as to non-mesh alternatives. The index surgical procedures, i.e., Anterior Prolift+M device, Posterior Prolift+M device, and TVT-O suburethral sling and cystoscopy, performed by Thomas Easter, M.D. on 04/08/2010 were indicated and appropriate. The procedure was performed within the standard of care with no evidence of surgeon error or deviation from the procedural steps. The operative note documents the use of hydro-dissection, describes an appropriate vaginal dissection, proper placement and fixation of the mesh in the anterior and posterior compartments, proper tensioning of the mesh, and no trimming of the vaginal mucosa. The TVT-O procedure was performed within the standard of care with no evidence of surgeon error or deviation from the procedural steps. The operative

note documents the use of wing catheter guide, proper placement and tensioning of the sling, normal cystoscopic exam, no trimming of the vaginal mucosa, and the use of estrogen vaginal cream packing at the end of the procedure. There was no evidence of any significant surgical complications, episodes of hypoxemia, excess blood loss, excess surgical duration, or surgical site contamination in the records. The patient was discharged from the hospital the day after surgery and without complications.

Terri Freeman did not have, at the time of the index surgery, any medical or historical factors, which increased her risk for dyspareunia, pelvic pain, vaginal distortion and mesh contraction, vaginal pain, buttock pain, urinary retention, voiding disorder, or hypertonic pelvic floor disorder. At the time she was 57 years old, and was taking medication for hypertension (Zestril), and GERD (Prilosec. Her surgical history included total abdominal hysterectomy and BSO (1979), cardiac ablation (2006). cholecystectomy, and appendectomy. She was a non-smoker. At the time of the implant Terri Freeman had no prior history of bleeding disorders, coronary artery disease, heart disease, renal disease, active pelvic or vaginal infections, active urologic infection, collagen or connective tissue disorders, autoimmune disease, diabetes, chronic pain syndromes, or malnutrition. She had no history of peripheral arterial disease, hypersensitivity to polypropylene, or small vessel disease. At the time of implant Mrs. Freeman had no prior pelvic radiation, no evidence of urogenital atrophy, and no prior vaginal reconstructive procedures. Intra-operatively there is no evidence of improper surgical technique, bladder or urethral injury, excess mesh tension, compromise of vaginal vascularization, or contamination of the sterile field. Post-operatively Mrs. Freeman did not have evidence of prolonged or urethral catheterization, surgical site infection, vaginal manipulation or sexual activity in the early post-operative period.

To date, as a result of the Total Prolift+M devices and the TVT -O sling mesh , their effect on her vaginal tissue, and the necessary multiple revision procedures, and complications of those revision procedures , Terri Freeman has endured dyspareunia, pelvic pain, vaginal distortion and mesh contraction, vaginal pain, buttock pain, urinary retention, voiding disorder, and hypertonic pelvic floor disorder. Since the implant of the Prolift+M devices and the TVT-O sling mesh Mrs. Freeman has required multiple surgical revision procedures under general anesthesia, pelvic abscess requiring an invasive drainage procedure, multiple hospital admissions, multiple emergency room visits, additional medical provider visits, multiple additional vaginal exams, multiple visits for physical therapy, multiple prescription medications, multiple additional diagnostic tests, and multiple imaging procedures.

A. Differential Diagnosis Regarding Vaginal Pain and Dyspareunia

To a reasonable degree of medical certainty, there is no cause for the vaginal pain and dyspareunia Mrs. Freeman has experienced other than the Prolift+M polypropylene implants, and the indicated and medically-necessary revision procedures and their complications, and their effects on

surrounding tissue. The Prolift+M mesh caused chronic inflammation (Pathology 12/21/16) which caused excess scarring in the tissues and artificially restricted the movement of the vagina, the pelvic floor, and its associated structures. The excess scarring caused nerve damage/ entrapment causing the development of pain. The Prolift+M mesh and the tissue changes was the primary cause of her new onset vaginal pain/dyspareunia. These changes are due to the characteristics of the Prolift+M mesh. The relatively high stiffness, low effective porosity especially under tension, and contraction of the Prolift+M mesh all contribute to negative tissue reactions such as bridging fibrosis, and poor tissue in-growth. The pore size under normal physiologic forces was inadequate to allow proper tissue in-growth in the mesh. The result of this, in Mrs. Freeman's case, increased chronic tissue inflammation evidenced by vaginal spotting, malodorous vaginal discharge, and resultant pain. This inflammation results in excess scar fibrosis, further mesh contraction, and further entrapment of nerve fascicles in the mesh scar resulting in chronic vaginal pain. Mrs. Freeman had no signs and symptoms of other conditions, endometriosis, pelvic masses, pelvic congestion syndrome, pelvic organ prolapse, hormonal variations, mesh erosion, endometriosis or pelvic infection, as an etiology of her chronic vaginal pain. There is no evidence of genitourinary conditions such as recurrent UTI, Urethral diverticulum, stone disease, interstitial cystitis, or neoplasia. There is no evidence of GI conditions such as active IBD, IBS, diverticulitis, fistulae, fissures, malignancy or bowel obstruction. There was no pre-operative evidence of pelvic floor hypertonic disorder, fibromyalgia, chronic pain syndromes, spinal cord injury or disease,

Despite multiple mesh revision procedures Mrs. Freeman has not had an improvement in the severity of dyspareunia and vaginal pain which she experiences. This is further evidence of the effects the Prolift+M implants, and the indicated and medically-necessary revision procedures and their complications, have had on her vaginal tissues. Terri Freeman continues to experience vaginal pain and dyspareunia and based upon the record she is unable to engage in vaginal sexual activity with her husband due to the severe pain she experiences.

Another substantial factor in causing the scarring and resulting shrinkage and injuries is the degradation of the Prolift+M and TVT-O mesh materials in the body. Degradation of polypropylene fibers in explanted mesh constructs has been identified and associated with surface changes on both light and Scanning Electron Microscopy. Increase in surface roughness can cause greater adherence of bacteria to the material resulting in ongoing tissue reaction. The degradation of the mesh will also increase the inflammatory response and tissue damage. Ongoing tissue reaction increases the risk of subsequent breakdown.

B. Differential Diagnosis Regarding Vaginal Contraction and Anatomic Distortion of the Vagina

To a reasonable degree of medical certainty, there is no cause for the vaginal contraction and

anatomic distortion of the vagina that Mrs. Freeman has experienced other than the Prolift+M polypropylene implants, and the indicated and medically-necessary revision procedures and their complications, and their effects on the surrounding tissue. Contraction of polypropylene surgical mesh in the body has been described in multiple peer-reviewed publications. This phenomenon results in long-term complications, including erosion, loss of elasticity, mesh contraction, nerve damage, and vaginal scarring. Ethicon was aware of this problem as early as January of 2005 (Ethicon Axel to Berthier memo 11 Jan 2005) when Axel Arnaud suggested adding the following statement to the Prolift IFU:

> WARNING: Early clinical experience has shown that the use of mesh through a vaginal approach can occasionally/uncommonly lead to complications such as vaginal erosion and retraction which can result in an anatomical distortion of the vaginal cavity that can interfere with sexual intercourse. Clinical data suggest the risk of such a complication is increased in case of associated hysterectomy. This must be taken in consideration when the procedure is planned in a sexually active woman.

Mrs. Freeman had no signs or symptoms of other conditions, such as vaginal trauma, foreign body, malignancy, prior pelvic radiation therapy, chronic vaginal infection, vaginal cysts, pelvic mass, endometriosis or pelvic infection, as an etiology of her vaginal contraction or anatomic distortion of the vagina. The Prolift+M mesh caused a significant tissue reaction with chronic inflammation. The result of this increased chronic tissue inflammation, in Mrs. Freeman's case, was evidenced by vaginal spotting, malodorous vaginal discharge, and resultant pain. Tissue reaction to the mesh and the mesh erosions caused excess scarring in the tissues and artificially restricted the movement of the vagina, the pelvic floor, and its associated structures. This was identified by multiple physicians including Dr. Easter, Dr. Siddighi (FPMRS), and Dr. Kim (FPMRS) These changes are due to the characteristics of the Prolift+M mesh, and the effects of indicated and medically-necessary revision procedures and their complications. The relatively high stiffness, low effective porosity especially under tension, and contraction of the Prolift+M mesh all contribute to negative tissue reactions such as bridging fibrosis, and poor tissue in-growth. The design of the Prolift resulted in severe scarring resulting in tissue contraction and distortion. The dense scarring identified by examination of Terri Freeman, at the left vaginal wall extending to the left side, associated with significant pain to palpation in this area is clinical evidence of these effects. The multiple revision procedures Mrs. Freeman to treat the Prolift+M effects also create tissue changes and scarring which can add to the process of contraction and vaginal contraction and anatomic distortion of the vagina.

Another substantial factor in causing the scarring and resulting shrinkage and injuries is the degradation of the Prolift+M and TVT-O mesh materials in the body. Degradation of polypropylene fibers in explanted mesh constructs has been identified and associated with surface changes on both light and Scanning Electron Microscopy. Increase in surface roughness can cause

greater adherence of bacteria to the material resulting in ongoing tissue reaction. The degradation of the mesh will also increase the inflammatory response and tissue damage. Ongoing tissue reaction increases the risk of subsequent breakdown.

C. Differential Diagnosis Regarding Hypertonic Pelvic Floor Disorder/Abdominal Pain

To a reasonable degree of medical certainty, there is no cause for the hypertonic pelvic floor disorder(HTPFD), and its clinical effects such as severe pelvic pain, difficulty with defecation, lower abdominal pain, left sided pelvic pain , reduced ability to walk, stand , or perform routine ADLs such as housework that Terri Freeman experienced other than the Prolift+M polypropylene implants, and the indicated and medically-necessary revision procedures and their complications, and their effects on surrounding tissue. Prior to implantation of the Prolift+M and TVT-O devices Terri Freeman did not have a history of constipation or left side abdominal pain. She had no evidence of defecatory or voiding dysfunction. Mrs. Freeman had no history or signs and symptoms of other conditions, such as chronic vaginal infection, severe vaginal atrophy, trauma, pelvic mass, pelvic nerve disorders, endometriosis or pelvic infection, as an etiology of her hypertonic pelvic floor disorder/vaginal pain and pressure. Prior to the implant procedure there is no evidence in the record identifying HTPFD by any examiners. On 08/02/15 Dr. Abdelkarim performed colonoscopy and EGD for abdominal pain with no etiology of the pain identified. On 11/17/15 Dr. Easter documents intractable pain and pelvic floor spasm which was severe enough to warrant steroid injection and possible surgery. On 10/20/16, at LLUMC Physical Therapy, vaginal exam is consistent with HTPFD. On 10/21/16, Dr. Kim identified a tight vaginal wall with pain throughout, which is consistent with HTPFD. Examination also revealed extensive scarring - consistent with the contraction and scarring of the Prolift+M and TVT-O mesh implants as the etiology of Mrs. Freeman's description of “The scar tissue had drawn everything in and I'm very small in vaginal opening, everything has pulled in. The bladder sling got too tight, wasn't emptying my bladder, Dr. Siddighi removed the bladder sling" noted on 10/13/16.

Scarring in the tissues artificially restricts the movement of the vagina, and the pelvic floor. The excess scarring causes tissue shrinkage resulting in nerve damage/entrapment causing the development of pressure and pain. Pain can result in muscle hypertonicity which reduces blood flow in the effected muscle. Ischemia will cause the release of tissue cytokines resulting in an increased inflammatory response in the pelvic floor muscles. Pelvic floor hypertonicity, to a high degree of medical certainty, is a substantial contributing factor to Terri Freeman's symptoms of constipation, lower abdominal pain, buttock pain, and voiding dysfunction, as these are known symptoms of the disorder. Mrs. Freeman has no signs and symptoms of other conditions, such as chronic vaginal infection, IBD, bowel obstruction, colonic strictures trauma, pelvic mass, pelvic nerve disorders, spinal nerve disorders, peripheral nerve disorders, hip abnormalities, endometriosis or pelvic infection, as an etiology of her hypertonic pelvic floor disorder or its resultant symptoms.

Another substantial factor in causing the scarring and resulting shrinkage and injuries is the degradation of the Prolift+M and TVT-O mesh materials in the body. Degradation of polypropylene fibers in explanted mesh constructs has been identified and associated with surface changes on both light and Scanning Electron Microscopy. Increase in surface roughness can cause greater adherence of bacteria to the material resulting in ongoing tissue reaction. The degradation of the mesh will also increase the inflammatory response and tissue damage. Ongoing tissue reaction increases the risk of subsequent breakdown.

D. Differential Diagnosis Urinary Retention/Long-Term Voiding Dysfunction

To a reasonable degree of medical certainty, there is no cause for the urinary retention and voiding dysfunction (elevated PVR, low flow and increased bladder pressure) Mrs. Freeman has experienced other than the TVT-O polypropylene implant and its effects on surrounding tissue. The TVT-O device has caused excess scarring in the tissues and artificially restricted the movement of the bladder neck, urethra, and pelvic floor. The excess scarring and tissue fibrosis caused tissue shrinkage, resulting in sling contraction and tightening, as identified during revision surgery by Dr. Siddighi (“tight blue sling midurethral area"). Urinary retention and urinary frequency are well-known symptoms of urethral constriction and bladder outlet obstruction caused by excess sling tightness due to contraction of the tissue-mesh construct. Mrs. Freeman had no evidence of pre-implant baseline detrusor dysfunction, and Mrs. Freeman had no symptoms of bladder outlet constriction when she was discharged from the hospital. The symptom of urinary hesitancy (difficulty emptying the bladder) is noted to have started 3-4 weeks before the ER visit at San Antonio Hospital on 10/25/10, which would be at least 5 months after the TVT-O was implanted. On 10/26/10 Dr. Easter's exam documents the bladder is not tender. On 12/31/15 during a post-op visit with Dr. Easter a urinary catheter was removed and it is noted that there were no problems with the catheter. On 04/12/16 during an office visit with Dr. Easter for post-op care it is documented that the patient needs to strain in order to urinate and that this has been a problem since surgery. On 05/19/16 an office visit with Dr. Tasia (San Antonio Urology Group) for urinary retention is documented. Patient reports need to push to void. The PVR by bladder scan was 254 cc. and the assessment included urinary retention. On 07/11/16 during a visit at Loma Linda University Medical Center it is documented that on multichannel urodynamic Mrs. Freeman does have some increased pressure with low flow and has an elevated postvoid residual of 280 mL after voiding 414 mL. The diagnosis included urinary retention. This progression of her symptoms is evidence of the ongoing nature of this process of sling contraction and tightening. After the removal of the intravaginal section of the sling by Dr. Siddighi, and the removal of the residual sling by Dr. Ja-Hong Kim, urodynamics was repeated for LUTS. On 05/16/17 VUDS revealed the PVR was 60 with slow flow and normal bladder pressure and no detrusor overactivity during voiding. This is consistent with no bladder outlet obstruction (BOO), no urinary retention, and an effect on the innervation of the bladder and urethra by multiple surgeries for mesh revision. The

alleviation of the BOO by removal of the TVT-O mesh sling is further evidence that, to a high degree of medical certainty, that the TVT-O mesh sling was a substantial contributing factor to the urinary retention and voiding dysfunction Mrs. Freeman suffered.

E. Differential Diagnosis Regarding Urinary Frequency/Lower Urinary Tract Symptoms (LUTS)/Urge Incontinence/Positional Urine Loss

To a reasonable degree of medical certainty, there is no cause for the overactive bladder, urinary urgency, urinary frequency, positional urine loss, and urge urinary incontinence which Mrs. Freeman has experienced other than the Prolift+M and TVT-O polypropylene implants, their effects on surrounding tissue, and the effects of the indicated and medically-necessary revision procedures and their complications. Mrs. Freeman reports urinary urgency, urinary frequency, difficulty urinating and lack of bladder control (0/24/17 visit Dr. Ja-Hing Kim), but also has a slow urinary stream. Urodynamics studies performed are consistent with uninhibited detrusor contractions, normal compliance, 228 cc capacity (low), and detrusor overactivity associated with leakage at 23 cm H20. The LUTS Mrs. Freeman suffers from today are secondary to the bladder outlet obstruction resulting from the contraction and tightening of TVT-O mesh, and the tissue damage caused by the multiple revision procedures required to correct that condition. Multiple surgical procedures were performed which required dissection of the space between the bladder/urethra and the vagina. This area is referred to as the base of the bladder. The neural pathways required for normal bladder function include sensory, motor and autonomic nerves which travels through this area. With each surgical procedure these pathways are disrupted and injured. Each procedure carries a 10-15 % risk of causing de novo bladder dysfunction. There is no evidence that Mrs. Freeman has a neurologic condition, bladder mass, bladder foreign body, bladder stones, pelvic mass, advanced pelvic organ prolapse, urethral diverticulum, chronic urethritis, or other conditions which are the etiology of these injuries.

VI. Future Prognosis

Terri Freeman has suffered severe injuries that are permanent, and she will require ongoing and future medical care for her mesh related complications, which will add to the physical toll of this ordeal and continue to require the expenditure of money to pay for this care, and related items and travel. More specifically, it is more likely than not that she will continue to suffer from continuing vaginal pain, pelvic pain and dyspareunia, pelvic muscle spasm and pain, as a result of the scarring and nerve damage/ entrapment caused by the Prolift+M and TVT-O devices. Despite multiple revision procedures, multiple pelvic floor physical therapy session, and medication her vaginal pain, left abdominal pain, HTPFD, and buttock pain persists. The excess scarring caused tissue shrinkage resulting in mesh contraction and tissue banding resulting in nerve damage/ entrapment causing the development of pain. This excess scarring is due to the relatively high stiffness, low effective porosity especially under tension, and contraction of the Prolift+M mesh, all of which resulted in inadequate tissue in-growth, bridging fibrosis, and scar plate formation. As described

these tissue changes are progressive and permanent so that Terri Freeman will continue to have vaginal contraction, vaginal pain and dyspareunia, hypertonic pelvic floor disorder, and worsened constipation, LUTS, and urinary incontinence. The progression of her symptoms is further evidence of the ongoing nature of this process. Since a portion of the Prolift+M mesh, specifically the deep (proximal) arms of the Anterior and Posterior Prolift+M devices have not been removed, to a high degree of medical certainty, further physical therapy, office visits, medications, invasive diagnostic studies (e.g. cystoscopy) will be needed to manage her permanent chronic pain conditions.

VII. Conclusion

Based on the foregoing, including my first hand experience with the Prolift and Prolift+M devices, and the TVT-O device, it is my opinion that these devices, inclusive of the procedures for implantation, are/were unreasonably dangerous and defective, creating unreasonable risks of harm and a risk benefit profile – when all information about the dangerous aspects are known – which is unacceptable and should preclude use of the device. In addition, Ethicon failed to adequately warn of the risks of this device and procedure, further exacerbating the unreasonably dangerous nature of the device and procedure. As a result, Mrs. Freeman, who was a reasonable candidate for alternative procedures without the use of the Anterior and Posterior Prolift+M or TVT- O, suffered severe, permanent injuries and damage to her pelvis and vagina, rendering her a life-long chronic pain patient who is unlikely to ever again engage in normal, enjoyable sexual relations, and she will need ongoing medical care for the rest of her life.

I reserve the right to amend and/or supplement this report if new discovery or facts necessitate.

Submitted by,

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